Response to Office Action Summary 11/30/05 Examiner: Shumaya B. Ali

1. Claims were rejected under 35 U.S.C. 112 as not distinctly claiming the subject matter of the invention. Claims 4 and 10 were rewritten to show more clearly that what is claimed is the tubing.
2. In Claim 1 "the midpoint" was changed to "a midpoint" and 180 degrees was changed to 160.
3. Claims 16-19 were rejected as being incomplete. Claims 16-19 were canceled.
4. Claims 4 and 10 were rejected under 35 U.S.C. 102(a) as anticipated by the Wood application. Claims 4 and 10 were amended to show more clearly that what is being claimed is the tubing.
5. 35 U.S.C. 103(a) is used as a basis for rejecting claims 1, 3 and 5, 11. One figure showed a CPAP device worn under the nose with an arc-shaped nosepiece that appears similar to the vee-shape in my application. Other figures represent the same nosepiece in a less pronounced arc. I invented a similar device used for CPAP and am quite familiar with its design and operation. The shape is required to point the relatively large tubing towards the top of the ears and has nothing to do with positioning the nosepiece. If the body is a straight, horizontal section then the tubes will point horizontally coming out of the nosepiece and the large tubing cannot bend sharp enough to travel up and around the ear. The gas directing orifice is angled acutely because each one must be large enough to breathe through and yet still have the tips be at the same spacing as the nostrils. Each orifice tapers larger at the base in order to reduce flow resistance. For the columella (bridge of the nose) to fit in the middle in spite of the taper, the base of each orifice must be spaced farther apart than the nostrils. As a result the axis of each orifice must be angled towards the center so the tips are spaced properly. The invention of the Wood device is the use of the gas directing orifice for sealing the nostrils to prevent air from escaping and providing a means of anchoring the nosepiece in a fixed position. My device differs fundamentally in this respect. The gas directing orifices do not seal the nostrils and are not supposed to touch the nasal walls at all. They are at an acute angle to match the shape of the nose thus maintaining distance from the walls. Another main difference is the diameter of

the orifice is small in comparison to the nostril opening because air is breathed in the area surrounding the orifice rather than through it as in the CPAP device. The vee-shape of the nosepiece in my invention matches the contours of the face so it fits better but it also puts the center of gravity below the attachment points for the support tubing. This causes the cannula to remain upright as it hangs and this, in turn, allows extremely flexible support tubing to be used. The ease with which the tubing bends allows the wearer to move the head without the nosepiece being pushed or pulled out of position by reaction of the bending forces. Thus the nosepiece can be held in place with very little tension on the tubing and it is this tension that is the cause of most discomfort associated with cannulas. It is therefore evident that the vee-shape of the nosepiece is critical to at least one embodiment of this invention. In view of these major differences it would not be obvious for someone to read the Wood application for a nasally anchored CPAP device, look at the pictures, realize the shape could be modified to lower the center of gravity then realize it could be used in a different application where the device is not anchored and that one could use tubing that has not been successfully used up to that point in time. The Wood patent application states repeatedly that the nosepiece is retained in place by the engagement of the nares, or prongs to the nostrils. It goes on to say [0052] that his invention is not limited to CPAP devices but applies to any device having an interface that seals to a person's nasal airways. In summary, the applications for the device and mine are completely different and the reasons for having the nosepiece shape are also completely different. The Wood device cannot be used the same way as an oxygen cannula and, therefore, fails the field of endeavor test. Claims 5 and 11 are rejected under the same obviousness rule based on the teachings of two patent applications (Wood and Gunaratnam) and that a person skilled in the art could modify the device described in the Wood application using information from the G application. However, the information contained in these two documents is not applicable to my invention so it is not reasonable to assume that a skilled person could combine the two to make an oxygen cannula with features that are fundamentally different than the devices described in the two applications. The

Gunaratnam application teaches flexible tubing made of silicone with a hardness of about 50 Shore A but goes on to say they may be formed of any suitable material of any suitable hardness. It also teaches a swivel connector made of silicone with a hardness of 50-60A. In this case the swivel needs to be hard enough to remain engaged and maintain roundness. Silicone is a different material than PVC and 50-60A is at the hard end for silicone whereas that would be soft for PVC. Section 0262 of Gunaratnum application teaches the use of harder durometer silicone to prevent kinking. Also, despite the large number of variations presented in the application there were no instances of tubing used to position the unit as it is used in my invention. Therefore, this reference should not be considered prior art because it teaches in the opposite direction and is referring to a different material. Regarding obviousness, there is no information presented in the Gunaratnum application that teaches a person skilled in the arts that the hardness of molded parts performing an unrelated function could be used for tubing in a different application and to expect a degree of success where it is known that the hardness does not work well.

6. Claims 2,6-9,12-15 are allowed so no action taken.
7. An objection to the claims was made under 37 CFR 1.52(b) because the formatting of the application was improper (line spacing to small). The claims were amended with line spacing of 1.5.
8. A similar objection was made for the specification. This too was amended with 1.5 spacing.
9. On page 6 of the office action summary an objection to claim 10 is made about a vague connection between two descriptions of the same thing. The first is "a pair of spaced hollow extensions communicating with the interior of said tubular member" and the second is "a pair of hollow spaced extensions integral with and projecting therefrom". The first says the inside of everything is connected. In other words, air can flow from the body to the prongs or vice-versa. The second says the body and prongs are a common structure.

Additional comments

Both prior art references refer to CPAP devices. The applicant feels that these references do not pass the "field of endeavor test". That is that CPAP devices cannot be used in the same way as an oxygen cannula. CPAP devices are intended to seal the nasal passages and use tubing with a diameter large enough to breathe through comfortably. The cannula, on the other hand, uses tubing far too small to breathe through and the prongs do not seal to the nostrils and, in fact, should avoid contact with the nostrils at all. The diameter of the prong is small and causes little blockage of the nostril so that the wearer can breathe freely around it.

The Field of the Invention in the Wood patent relates to ventilation devices that seal against the nostrils. The Gunaratnum application relates to a nasal assembly used for the treatment of sleep apnea. CPAP devices can be used to administer supplemental oxygen to oxygen users that have sleep apnea. However this does not imply that a CPAP device can be used as a substitute for an oxygen cannula because it won't allow normal atmospheric breathing. Both references indicate an unsuitability for application of supplementary oxygen.

Non-obviousness

The insight was contrary to common wisdom because there was knowledge in the industry that a certain hardness of tubing was necessary to control orientation of the nosepiece.

One indication of non-obviousness is the fact that a large number of patents have been issued over a long period of time that address the very same problems solved by the present invention. Thus the field of endeavor has had considerable scrutiny and anything that made as much of an improvement as this would have been used long ago if it were obvious. This is true for each individual improvement as well as the combination of some or all.

Persons in the industry would not have a reasonable expectation of success. (2143.02) using soft tubing.

No information presented in prior art is helpful to making this invention work as well as it does.

Prior art has tried and failed to solve the problems solved by this invention

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